IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI

Plaintiffs,

v.

Civil Action No. 3:14-cv-07869(MAS)(LHG) Civil Action No. 3:14-cv-08082(MAS)(LHG) Civil Action No. 3:15-cv-02631(MAS)(LHG)

FRESENIUS KABI USA, LLC,

Defendant.

SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI

Plaintiffs,

v.

Civil Action No. 3:14-cv-08079(MAS)(LHG) Civil Action No. 3:15-cv-02520(MAS)(LGH)

ACCORD HEALTHCARE, INC.,

Defendant.

SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI

Plaintiffs,

v.

Civil Action No. 3:14-cv-08081(MAS)(LHG) Civil Action No. 3:15-cv-02521(MAS)(LHG)

BPI LABS, LLC AND BELCHER PHARMACEUTICALS, LLC,

Defendants.



SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI

Plaintiffs,

v.

Civil Action No. 3:15-cv-00287(MAS)(LHG) Civil Action No. 3:15-cv-01835(MAS)(LHG)

APOTEX CORP. AND APOTEX, INC.,

Defendants.

SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI

Plaintiffs,

v.

Civil Action No. 3:15-cv-00289(MAS)(LHG) Civil Action No. 3:15-cv-01836(MAS)(LHG)

BRECKENRIDGE PHARMACEUTICAL, INC.,

Defendant.

SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI

Plaintiffs,

v.

MYLAN LABORATORIES LTD.,

Defendant.

Civil Action No. 3:15-cv-00290(MAS)(LHG) Civil Action No. 3:15-cv-03392(MAS)(LHG)



SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI

Plaintiffs,

v.

Civil Action No. 3:15-cv-00776(MAS)(LHG) Civil Action No. 3:15-cv-03107(MAS)(LHG)

ACTAVIS LLC,

Defendant.

SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI

Plaintiffs,

v.

DR. REDDY'S LABORATORIES, INC. AND DR. REDDY'S LABORATORIES, LTD.,

Defendants.

SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI

Plaintiffs,

v.

GLENMARK PHARMACEUTICALS, INC., USA and GLENMARK PHARMACEUTICALS LTD.,

Defendants.

Civil Action No. 3:15-cv-02522(MAS)(LHG)

Civil Action No. 15-cv-02523(MAS)(LHG)

JOINT CLAIM CONSTRUCTION AND PREHEARING STATEMENT

Pursuant to Local Patent Rule 4.3 of the United States District Court for the

District of New Jersey and the Court's Pretrial Scheduling Order entered June 12, 2015 (C.A.

No. 14-7869, ECF No. 23), plaintiffs Sanofi-Aventis U.S. LLC, Aventis Pharma S.A., and



Sanofi ("Plaintiffs") and defendants Fresenius Kabi USA, LLC ("Fresenius"); Accord Healthcare, Inc. ("Accord"); BPI Labs, LLC and Belcher Pharmaceuticals, LLC (collectively, "BPI-Belcher"); Apotex Corp. and Apotex Inc. (collectively, "Apotex"); Breckenridge Pharmaceutical, Inc. ("Breckenridge"); Mylan Laboratories Limited ("Mylan"); Actavis LLC ("Actavis"); Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (collectively, "DRL"); and Glenmark Pharmaceuticals Inc., USA (formerly known as Glenmark Generics Inc., USA) and Glenmark Pharmaceuticals Ltd. (collectively, "Glenmark") (all collectively, "Defendants") hereby provide their Joint Claim Construction and Prehearing Statement concerning U.S. Patent Nos. 5,847,170 ("the '170 patent"), 7,241,907 ("the '907 patent"), and 8,927,592 ("the '592 patent") (collectively "Patents-In-Suit").

I. BACKGROUND

This is a Hatch-Waxman Act patent action. Plaintiffs assert, among other things, that Defendants infringed the Patents-In-Suit by filing a New Drug Application ("NDA") and/or an Abbreviated New Drug Application ("ANDA") pursuant to 21 U.S.C. §§ 355(b)(2) and/or (j) (§ 505(b)(2) or § 505(j) of the Federal Food, Drug and Cosmetic Act) with the U.S. Food and Drug Administration seeking approval to market proposed drug products, which are as follows:

- a. For Fresenius: Cabazitaxel Injection, 60 mg/3 mL solution ("Fresenius's NDA Product") and Cabazitaxel Injection, 60 mg/1.5 mL solution ("Fresenius's ANDA Product");
- b. For Accord: Cabazitaxel Injection, 60 mg/1.5 mL ("Accord's ANDA Product") and Cabazitaxel Injection, 20 mg/mL, 3mL ("Accord's NDA Product");
- c. For BPI-Belcher: Cabazitaxel, 60 mg/1.5 mL solution for intravenous infusion ("BPI-Belcher's ANDA Product");



- d. For Apotex: Cabazitaxel Injection, 60 mg/1.5 mL ("Apotex's ANDA Product");
- e. For Breckenridge: Cabazitaxel Solution, IV, 60 mg/1.5 mL ("Breckenridge's ANDA Product");
- f. For Mylan: Cabazitaxel Injection [60 mg/1.5 mL] [40 mg/mL] ("Mylan's ANDA Product");
- g. For Actavis: Cabazitaxel Injection, 10 mg/mL (40 mg/4 mL, 60 mg/6 mL)("Actavis's NDA Product");
- h. For DRL: Cabazitaxel Solution for Infusion, 60 mg/1.5 mL ("DRL's ANDA Product"); and
- For Glenmark: Cabazitaxel for Injection, 60 mg/1.5 mL (40 mg/mL) ("Glenmark's ANDA Product") (collectively "Defendants' Cabazitaxel Products").

Plaintiffs also assert that Defendants will infringe the Patents-In-Suit if Defendants commercially make, use, offer to sell, or sell Defendants' Cabazitaxel Products, or import Defendants' Cabazitaxel Products into the United States, or induce or contribute to any such conduct.

Defendants allege that they do not and will not infringe the Patents-In-Suit and that the Patents-In-Suit are invalid.

II. CONSTRUCTION OF TERMS

A. Construction of Terms on Which the Parties Agree

In accordance with Local Patent Rule 4.3(a), Plaintiffs and Defendants (collectively the "Parties") have agreed to the construction of the following terms.

With respect to claims 7 and 9 of the '592 patent, the Parties agree that "AUC of about 991 ng·h/mL (CV 34%)" and "plasma clearance of 48.5 L/h (CV 39%)" do not need to be construed. The Parties do not thereby propose a construction for either of those terms.



DOCKET

Explore Litigation Insights



Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time** alerts and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.

